

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application of:

Takayuki ONIKI et al.

Application No.: 10/584,192

Confirmation No.: 3847

Filed: June 23, 2006

Art Unit: 1612

For: NONAQUEOUS GEL COMPOSITION FOR
TOOTH WHITENING AND TOOTH
WHITENING SET

Examiner: D. SUTTON

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
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Sir:

I, Takayuki ONIKI, do declare and say as follows:

1. I am a co-inventor of above-identified application.
2. I have read the Final Office Action dated March 17, 2010 in the above-identified application and understand its contents.
3. I have read and understand the contents of the references cited in the March 17, 2010 Office Action, including the references of WO 03/030851 (hereinafter referred to as "Oniki") and U.S. Patent Applic. Public. No. 2001/0007652 (hereinafter "Takeda '652").
4. In the March 17, 2010 Office Action, the Examiner refers Applicants to the disclosure of shellac in Takeda '652, and that components disclosed in Oniki and Takeda '652 would reach the surface of the teeth (see paragraph bridging pages 3-4 of Office Action). Also,

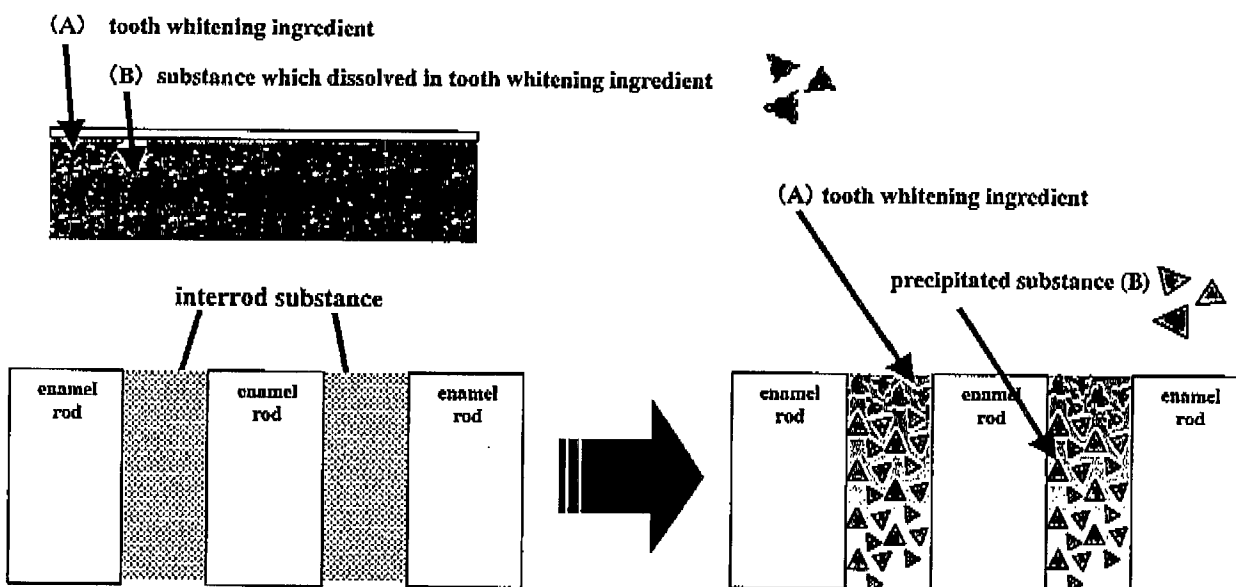
the Examiner states that Applicants have not provided any support for the allegation that the shellac of the cited references would not penetrate into the teeth and instead precipitate on the surface of the teeth (Office Action, page 4, third full paragraph and bottom of page 3). In response, I provide the following technical explanation of the present invention and how the compositions in Takeda '652 and Oniki work.

5. The present invention is directed to a tooth whitening set for reversibly making tooth look white in the presence of water from saliva without chemical bleaching reactions due to a peroxide, comprising a nonaqueous gel composition (i.e., water content of less than 3% by weight of the total amount of the composition and being free of a peroxide) for tooth whitening and a tool for its application (i.e., tape, sheet or film) which is detachably fitted to teeth while holding it.

The nonaqueous gel composition comprises ingredients (A), (B) and (C):

- Ingredient (A) is the tooth whitening ingredient (in an amount of 50.0 to 99.5 % by weight of the total amount of the composition);
- Ingredient (B) is a substance (i.e., whitening effect endurance improver) which dissolves in said tooth whitening ingredient and is precipitated by an aqueous solution of calcium chloride (and is present in an amount of 0.1 to 10 % by weight of the total amount of the composition); and
- Ingredient (C) is a gelling agent and used in an amount of 0.1 to 15 % by weight of the total amount of the composition.

In the present invention, ingredients (A) and (B)) penetrate into the enamel layer of the tooth (e.g., into the interrod space between enamel rods). With the present invention, the substance (B) dissolves in the tooth whitening ingredient, is precipitated by water in saliva to prevent the tooth whitening ingredient in the enamel from easily leaching out, and changes the optical properties of the enamel without chemical reactions so that the enamel looks apparently cloudy and whiter than original. I refer to the following depiction:



Thus, the present invention achieves such a whitening effect by changing the optical properties of the enamel without using any peroxide, thereby giving an advantage of being a safer whitening composition. Also, teeth look white while at the same time permits teeth to restore their original color in the presence of water (from saliva), and the whitening effect endures for a relatively long time.

6. Takeda '652 and Oniki use aqueous teeth whitening compositions, wherein the whitening effects are achieved in a different manner versus the present invention.

The Takeda '652 dentifrice composition contains significant amounts of water as an essential component, including all of the working examples of Takeda '652. For instance, Examples 1 and 2 (at page 2) contain 31.4% and 28.6% purified water, respectively. Among the Examples in Takeda '652, Example 3 contains the least amount of water. Example 3 of Takeda is as follows:

Components	wt. %
Silicic acid anhydride	15.0
Sorbitol (70%)	63.0
Glycerol	3.0
Propylene glycol	8.0
Shellac	2.0
Sodium carboxymethyl cellulose	0.8
Sodium lauryl sulfate	1.5
Flavor	1.3
Sodium saccharin	0.1
Methyl p-hydroxybenzoate	0.1
Sodium benzoate	0.1
Purified water	3.1
Total	100.0

Although the amount of water is 3.1 wt%, sorbitol (70%) contains 30 wt% water. Therefore, 63.0 wt% of sorbitol (70%) contains 18.9 wt% water, and thus the total water content of the toothpaste composition of Example 3 is $3.1 \text{ wt\%} + 18.9 \text{ wt\%} = 22 \text{ wt\%}$.

Further, the Takeda '652 composition is applied to teeth as the conventional application method of dentifrice compositions which is tooth brushing (see, e.g., paragraphs [0021] and [0023] of the reference). The invasion of saliva further dilutes the Takeda '652 compositions. Example 3 is also a toothpaste (see paragraph [0025]).

The compositions in Oniki also contain water as is apparent from the Examples disclosed therein.

A toothpaste composition containing a considerable amount of water does not fully give the whitening effect as achieved by the present invention. Such an inferior whitening effect is

seen from Comparative Example 5 of Table 4 of the present specification (an "X" value is obtained; see specification at page 24, lines 26-34). This is because the infiltration of polyols into the tooth enamel would not be attained due to dilution of the Takeda '652 and Oniki compositions due to the presence of saliva, in addition to the considerable amount of water already present in the compositions (before use).

Takeda '652 also discloses the following:

[0018] A process for producing the dentifrice compositions according to the present invention is the same as the production process for the conventional dentifrice compositions except that the wax or shellac is dissolved in a substance commonly used in the conventional dentifrice compositions, such as propylene glycol. FOMBLIN HC (Trade Mark) is insoluble in almost all solvents, but may be mixed for use with, for example, propylene glycol or glycerol because its emulsifiability and dispersibility are good. The disinfectant may also be dissolved or dispersed for use in a solvent generally used in dentifrice compositions.

Although in Takeda '652 shellac is dissolved in a solvent such as propylene glycol upon preparation of the dentifrice composition to mix it with the other components, shellac is not present in a dissolved state in the resulting dentifrice. Instead, since a considerable amount of water is present in the dentifrice composition, shellac is present as an undissolved and dispersed state in the resulting solid or paste dentifrice composition. In addition, the solvent capable of dissolving shellac such as propylene glycol is only present in an insufficiently small amount in the dentifrice composition. Thus, the shellac does not infiltrate the enamel of the teeth. Shellac or wax may cover the surface of teeth in a pasty state, which also prevents infiltration of polyols (*i.e.*, the inventive component (A)). The precipitated shellac or wax on the surface of teeth is brittle and easily removed from the surface of teeth. Thus, the whitening effect does not endure for a long time when compared to the present invention.

The present invention is a nonaqueous gel composition, wherein the water content is less than 3% by weight of the total amount of the composition. In the present invention, shellac is in a dissolved state. As depicted above, shellac dissolves in ingredient (A) and penetrates into the enamel of teeth. Then, the shellac precipitates but remains within the interrod space between the enamel

rods. Such a superior and lasting whitening effect is achieved only after the infiltration of ingredients (A) and (B) into the enamel of teeth.

7. I hereby declare that all statements made herein of my own knowledge are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated this 11 day of Aug, 2010

By: 鬼木 隆行
Takayuki ONIKI